

U.S. Food and Drug Administration
Dept. of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

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December 7, 2000

To Whom It May Concern:

I have just found out that the FDA requested Glaxo to withdraw Lotronex, a drug made by Glaxo Wellcome, from the market. From all the information that I could gather, I understand the reasoning behind the decision, however I felt it was in haste.

I am a husband of an IBS sufferer of 10 years. My wife's IBS symptoms progressively got worse and it has effected our marriage, her working ability, and overall mental state of the both of us. She tried Lotronex in early 2000 for the first time and for the first time in 10 years, her intestinal cramping stopped. For the first time without problem, she could eat almost anything she wanted. She became a totally new person and she felt like a normal human being, not being slaved to a bed or bathroom. Granted, the beginning dosage was too powerful for her and gave her bad constipation, but after much trial, the right dosage was about 1/8th (one eighth) of the originally prescribed dosage. So, in my opinion, the drug is not a killer, the doctors were just prescribing too much of a dosage.

Now that Lotronex has been pulled from the market, she is not able to refill her outstanding prescription and the cramping is coming back. She is sliding back into her deteriorated state and the strain of the illness is once again affecting our marriage. I'm sorry for those who became deathly ill or died. But as with all drugs, should the few sad instances prohibit the majority from feeling free of the jail sentence called IBS? Couldn't the drug be safer if given out in a much smaller dosage? I just think it was decided on too quickly and heartedly request that Lotronex be returned to the market. IBS sufferers are all crying in the chat rooms and web support groups. It's just not fair. I felt I needed to voice my opinion, thank you.

Sincerely,

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